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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,483	12/31/2003	Michael S. Collins	ZIM0391	1206

7590 08/16/2007  
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EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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08/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/749,483

Applicant(s)

COLLINS ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19 and 25 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-16,21-24 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3-4, 8-16 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 8 and 21 it is unclear what is being claimed. If the first and second components are engageable in a direct self-locking taper relationship, it is unclear why a sleeve is necessary.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

In light of the rejection under 35 USC 112 second paragraph, claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfaff et al. (US 6,607,560).

Pfaff et al. disclose a modular joint prosthesis having a first component 3 with a female junction element 4 and a second component 2 with a male junction element 5

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receivable within the female junction element and a hollow resilient sleeve 4 that is capable of being rolled upon itself in a ring-like configuration (Figs. 1 and 2, col. 2, lines 22-30, col. 3, lines 3-14 and col. 4, lines 12-36).

In light of the rejection under 35 USC 112 second paragraph, claims 1, 3, 4, 8, 10, 14-16, 21, 23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bunz (US 6,802,866).

Bunz discloses a modular joint prosthesis having a first component 3 with a female junction element and a second component 2 with a male junction element receivable within the female junction element in a self-locking taper relationship and a hollow resilient sleeve 6 that is capable of being rolled upon itself in a ring-like configuration (Figs. 1-11, col. 3, lines 21-67 and col. 4, lines 1-21).

The method steps of claim 21 are inherently performed when the Bunz prosthesis is assembled.

In light of the rejection under 35 USC 112 second paragraph, claims 8-10, 13, 14, 16, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Averill et al. (US 4,921,500).

Averill et al. disclose a modular orthopedic implant having a femoral stem or "first component" 10 with a male junction element 18 and a femoral head component or "second component" 20 with a female junction element 32 and an adaptor or "hollow sleeve" 40 with grooves 66 extending circumferentially around the outer surface 52 of the sleeve that maintain the first and second components in an assembled condition wherein the stem and head components are made of a biocompatible metal (Fig. 3, col. 3, lines 16-68, col. 4 and col. 5, lines 1-51).

The method steps of claim 21 are inherently performed when the Averill et al. modular implant is assembled together.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz (US 6,802,866) in view of Draenert (US 6,682,566).

Bunz discloses all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during a surgical procedure.

Draenert teaches providing a modular prosthesis with components having different sizes so that the prosthesis can be assembled for a specific patient (Fig. 1, col. 2, lines 46-67, cols. 3-4 and col. 5, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Bunz components in a variety of sizes, i.e., provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz (US 6,802,866) in view of McLean (US 2002/0116068).

Bunz discloses all the elements of the claimed invention except for the use of a polymer to construct either the male or the female junction elements.

McLean teaches the use of synthetic materials such as metals, ceramics or plastics to construct prosthetic components (para [0053]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the Bunz components of metal and polymer, since it has been held to be within the general skill of a worker in the art to select a known

material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfaff et al. (US 6,607,560) in view of Fallin (US 5,108,452).

Pfaff et al. disclose all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during a surgical procedure.

Fallin teaches providing various prosthesis components in kit form so that a prosthesis can be custom fitted to a patient by a surgeon (Fig. 1 and col. 1, lines 12-39).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Pfaff et al. components in a variety of sizes, i.e., provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Averill et al. (US 4,921,500) in view of Fallin (US 5,108,452).

Averill et al. disclose all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during a surgical procedure.

Fallin teaches providing various prosthesis components in kit form so that a prosthesis can be custom fitted to a patient by a surgeon (Fig. 1 and col. 1, lines 12-39).

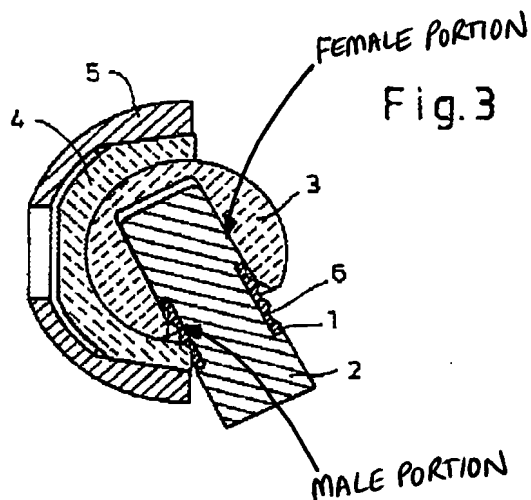
It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Averill et al. components in a variety of sizes, i.e., provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

### ***Response to Arguments***

Applicants' arguments submitted under "REMARKS" in the response filed on May 17, 2007 have been fully considered.

Applicants' arguments with respect to the rejections over Pfaff et al. (US 6,607,560) are not persuasive because it is unclear what is being claimed. If the sleeve is necessary to hold the trial components together then how can the components be engageable in a direct, self-locking taper relationship?

Regarding the rejections of claims 1, 3, 4, 8, 10, 14-16, 21, 23 and 26 as being anticipated by Bunz, it is noted that Fig. 3 of Bunz clearly shows a modular orthopedic implant having a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore corresponding to the male portion wherein sleeve 6 has at least an outer portion or part that is engageable or "capable of engaging" with the female portion and an inner portion or part that is engageable or "capable of engaging" with the male portion. Figure 3 of Bunz is marked up below to illustrate features of Applicant's claimed invention.



Applicants' arguments with respect to the rejections of claims 8-10, 13-14, 16, 21 and 23 are not persuasive in light of the rejections under 35 USC 112 second paragraph.

***Allowable Subject Matter***

Claims 17-19 and 25 are allowed.

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

August 13, 2007

  
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